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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,018	05/16/2001	Edgar B. Cahoon	BB-1295	2583

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/856,018

Applicant(s)

CAHOON ET AL.

Examin r

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The amendment and election filed February 6, 2003 have been entered.

Claims 26-45 have been cancelled.

Claims 46-60 are newly submitted.

Applicant's election of Group I and SEQ ID NO: 15 and 16 in Paper No. 17 is

5 acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, in view of the cancellation of the previously pending claims and the submission of new claims, all pending claims are drawn to the elected invention and are examined in this office action.

10 Claims 46-60 are pending and are examined on the merits.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 46-50, and claims 51-60 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 Claim 46, part (b) is indefinite in the recitation of "a complement of the nucleotide sequence", since there would only be one complement that is of the same number of nucleotides and 100% complementary, and it should specify that the nucleotide sequence referred to is that recited in part (a). Amendment of the claim to read "the complement of the nucleotide sequence of (a)" would obviate the rejection.

In claims 47-50, "the default parameters" should be amended to read "said default parameters", for clarity.

5 Claims 46-60 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are drawn to an isolated polynucleotide encoding a polypeptide of SEQ ID NO: 16 or at least 70% identity thereto. The specification asserts that this polypeptide has diacylglycerol acyltransferase (DGAT) activity based on sequence comparisons with known or putative DGAT at pages 20-22. However, the sequence comparisons show that SEQ ID NO: 10 16 has as little as 30.9% sequence identity to a known DGAT and 65.9% sequence identity to a putative DGAT. In addition, the specification does not provide any additional information, such as an enzyme assay, to establish the utility of the claimed sequences. Furthermore, the claims are not limited to the sequence encoding SEQ ID NO: 16, but are broadly drawn to sequences that have at least 70% identity thereto, with no limitation that these sequences 15 encode a DGAT. Therefore, no substantial or well established utility has been provided for the claimed sequences.

Claims 46-60 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use 20 the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

5 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10 Claims 46-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated polynucleotide encoding a polypeptide of SEQ ID NO: 16 or at least 70% identity thereto. The specification asserts that this polypeptide has diacylglycerol acyltransferase (DGAT) activity based on sequence comparisons with known or putative DGAT at pages 20-22. However, the specification does not set forth what structural or physical features of this sequence result in
15 the claimed activity. In addition, most of the claims do not even specify what the functional activity of the polypeptide encoded by the DNA sequence would be.

 See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

20 “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe
25 human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . .”

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

5 Claims 46-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10 The claims are drawn to an isolated polynucleotide encoding a polypeptide of SEQ ID NO: 16 or at least 70% identity thereto. The specification asserts that this polypeptide has diacylglycerol acyltransferase (DGAT) activity based on sequence comparisons with known or putative DGAT at pages 20-22. However, the sequence comparisons show that SEQ ID NO: 16 has as little as 30.9% sequence identity to a known DGAT and 65.9% sequence identity to a putative DGAT. In addition, the specification does not provide any additional information, 15 such as an enzyme assay, to establish how to use the claimed sequences. Furthermore, the claims are not limited to the sequence encoding SEQ ID NO: 16, but are broadly drawn to sequences that have at least 70% identity thereto. The specification does not provide evidence that SEQ ID NO: 16 functions as a DGAT, much less any sequences that have sequence homology to it.

20 Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer

analysis of genome sequences is flawed, and “overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions” (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that “there are numerous cases in which proteins of very different functions are homologous” (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different molecular and cellular functions” (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode DGAT, one cannot conclude that these other sequences also encode enzymes having DGAT activity.

In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N).

5 Therefore, both the identification of other genes encoding DGAT activity, and the modification of plant lipid composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

Thus, given the unpredictability of identifying sequences that exhibit DGAT activity and modifying the lipid composition of a plant leaf; the lack of guidance in the specification for
10 identifying and characterizing any other sequences that exhibit DGAT activity; the lack of working examples of DGAT coding sequences, and the lack of working examples of other sequences that encode proteins having the same activity; and the breadth of the claims, and use of said genes or portions of said genes to modify a fatty acid; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

15

The claims are deemed free of the prior art as the prior art does not teach or suggest the polynucleotide of SEQ ID NO: 15 or a polynucleotide that encodes SEQ ID NO: 16 or a sequence at least 70% identical thereto.

20

No claims are allowed.

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Art Unit 1638


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.
April 18, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600